

Listing of Claims:

1. (Previously Presented) An orally consumable solid film comprising:

at least one water soluble polymer, and

an adsorption complex, said adsorption complex comprising at least one pharmaceutically active agent and at least one ion exchange resin as a taste masking agent; and

wherein the ratio of the at least one pharmaceutically active agent to the at least one ion exchange resin is about 1:3 to about 3:1; and wherein said orally consumable film is adapted to adhere to and dissolve in a mouth of a consumer.

2. (Previously Presented) The consumable solid film according to claim 1, wherein said water soluble polymer is selected from the group consisting of pullulan, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, tragacanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl polymer, amylose, high amylose starch, hydroxypropylated high amylose starch, dextrin, pectin, chitin, chitosan, levan, elsinan, collagen, gelatin, zein, gluten, soy protein isolate, whey protein isolate, casein and mixtures thereof.

3. (Previously Presented) The consumable solid film according to claim 2, wherein said water soluble polymer is pullulan.

4. (Previously Presented) The consumable solid film according to claim 1, wherein said pharmaceutically active agent is selected from the group consisting of antimicrobial agents, non-steroidal anti-inflammatory agents, antitussives, decongestants, anti-histamines, expectorants, anti-diaherrals, H₂-antagonists, proton pump inhibitors, central nervous system agents, analgesics and mixtures thereof.

5-13 (Cancelled)

14. (Previously Presented) The consumable solid film according to claim 1 wherein the pharmaceutically active agent provides from about 40 wt% to about 60 wt% of said adsorption complex.

15. (Previously Presented) The consumable solid film according to claim 14, wherein the ion exchange resin is a sulfonated polymer comprising polystyrene cross-linked with divinylbenzene.

16. (Previously Presented) The consumable solid film according to claim 14, wherein the ion exchange resin is a sulfonated polymer comprising polystyrene cross-linked with 8% of divinylbenzene, with an ion exchange capacity of about 4.5 to 5.5 meq/g of dry resin (H⁺-form).

17. (Previously Presented) The consumable solid film according to claim 16, wherein the ion exchange resin comprises irregularly-shaped particles ranging in size from about 47 to about 149 micrometers.

18. (Previously Presented) The consumable solid film according to claim 16, wherein the ion exchange resin comprises spherical particles ranging in size from about 45 to about 150 micrometers.

19. (Previously Presented) The consumable solid film according to claim 14, wherein the ion exchange resin comprises polystyrene cross-linked with 8% of divinylbenzene functionalized with a quaternary ammonium group, said ion exchange resin having an exchange capacity normally within a range of about 3 to about 4 meq/g of dry ion exchange resin.

20. (Cancelled).

21. (Previously Presented) The consumable solid film according to claim 14, wherein said water soluble polymer is pullulan, said pharmaceutically active agent is

dextromethorphan, and said taste masking agent is a sulfonated polymer ion exchange resin comprising polystyrene cross-linked with divinylbenzene.

22. (Previously Presented) The consumable solid film according to claim 21, comprising pullulan in an amount of about 40 to about 80 wt% of said film, dextromethorphan in an amount of about 5 to about 40 wt% of said film, and sulfonated polymer ion exchange resin in an amount of about 5 to about 40 wt% of said film.

23-24 (Cancelled)

25. (Currently Amended) A method for preparing the consumable solid film of claim 1, said method comprising:

dissolving the water-soluble polymer in water to provide an aqueous solution;

mixing water soluble film former and stabilizing agent to provide a solid-film forming mixture;

combining said solid-film forming mixture and said aqueous solution to provide a hydrated polymer gel;

mixing oils to form an oil mixture;

admixing said oil mixture and said hydrated polymer gel to provide a uniform gel, said uniform gel comprising said pharmaceutically active agent and said taste masking agent at least one ion exchange resin;

casting the uniform gel on a substrate; and

drying the cast gel to provide said solid film.

26. (Currently Amended) The method of claim 25, wherein said aqueous solution comprises both said pharmaceutically active agent and said taste masking agent at least one ion exchange resin.

27. (Currently Amended) The method of claim 25, wherein said taste masking agent is an ion exchange resin, and said pharmaceutically active agent is sorbed to said

ion exchange resin without separating ion exchanged pharmaceutically active agent from unexchanged agent and counter ion salts.

28. (Previously Presented) An orally consumable solid film comprising a water soluble polymer, a pharmaceutically active agent and an ion exchange resin taste masking agent, wherein said ion exchange resin is present at a weight ratio to said pharmaceutically active agent of about 2:1 to about 1:2 and said orally consumable film is adapted to adhere to and dissolve in a mouth of a consumer.

29. (Previously Presented) The consumable solid film according to claim 28, wherein the ratio of ion exchange resin to pharmaceutically active agent is about 1:1.

30-32 (Cancelled).

33. (Previously Presented) The consumable film according to claim 22, wherein pullulan is present in said solid film in an amount of about 2 to about 6 mg/cm², dextromethorphan is present in said solid film in an amount of about 1.4 to about 2 mg/cm², and sulfonated polymer ion exchange resin is present in said solid film in an amount of about 1.4 to about 2 mg/cm².

34. (Previously Presented) The consumable solid film according to claims 22 or 33, further comprising:

about 0.01 to about 5 wt% of at least one stabilizing agent;
about 0.001 to about 0.1 wt% of at least one of at least one coloring agent;
about 0.01 to about 70 wt% water;
about 0.1 to about 15 wt% of at least one sweetening agent;
about 0.1 to about 15 wt% of at least one flavoring agent;
about 0.1 to about 4 wt% of at least one cooling agent;
about 0.1 to about 5 wt% of at least one surfactant;
about 0.1 to about 12 wt% of a triglyceride;

about 0.001 to about 5 wt% of a preservative;
about 0.01 to about 5 wt% of a polyethylene oxide compound; and
about 1 to about 20 wt% of propylene glycol.

35. (Previously Presented) The consumable solid film according to claim 1 wherein the pharmaceutically active agent comprises dextromethorphan or salt thereof or both.

36. (Previously Presented) The consumable solid film according to claim 1 wherein the pharmaceutically-active agent comprises phenylephrine or salt thereof or both.

37. (Previously Presented) The consumable solid film according to claim 2 wherein said water soluble polymer comprises polyvinyl alcohol.

38. (Previously Presented) The consumable solid film according to claim 2 wherein said water soluble polymer comprises hydroxypropyl cellulose.

39. (Previously Presented) The consumable solid film according to claim 1 wherein the pharmaceutically active agent comprises diphenhydramine or salt thereof or both.

40. (New) The consumable solid film according to claim 2, wherein said pharmaceutically active agent is selected from the group consisting of antimicrobial agents, non-steroidal anti-inflammatory agents, antitussives, decongestants, anti-histamines, expectorants, anti-diarrheals, H₂-antagonists, proton pump inhibitors, central nervous system agents, analgesics and mixtures thereof.

41. (New) The consumable solid film according to claim 1, wherein said film has a thickness of 0.009+ 0.002 in.

42. (New) The consumable solid film according to claim 1, wherein said film contains about 0.1% to about 10 wt% moisture.

43. (New) The consumable solid film according to claim 1, wherein said film contains about 3% to about 8 wt% moisture.

44. (New) The consumable solid film according to claim 1, wherein said film contains about 4% to about 7 wt% moisture.

45. (New) An orally consumable solid film comprising:

at least one water soluble polymer selected from the group consisting of pullulan, hydroxypropylmethyl cellulose, and hydroxypropyl cellulose, and mixtures thereof; and

an adsorption complex, said adsorption complex comprising at least one pharmaceutically active agent and at least one ion exchange resin as a taste masking agent; wherein said pharmaceutically active agent is selected from the group consisting of antimicrobial agents, non-steroidal anti-inflammatory agents, antitussives, decongestants, anti-histamines, expectorants, anti-diarrheals, H₂-antagonists, proton pump inhibitors, central nervous system agents, analgesics and mixtures thereof; and

wherein the ratio of the at least one pharmaceutically active agent to the at least one ion exchange resin is about 1:3 to about 3:1; and wherein said orally consumable film is adapted to adhere to and dissolve in a mouth of a consumer.

46. (New) The consumable solid film according to claim 45 wherein the pharmaceutically active agent comprises dextromethorphan or salt thereof or both.

47. (New) The consumable solid film according to claim 45 wherein the pharmaceutically-active agent comprises phenylephrine or salt thereof or both.

48. (New) The consumable solid film according to claim 45 wherein the pharmaceutically active agent comprises diphenhydramine or salt thereof or both.